Medical Coverage Policy
Policy Number – MP22-030E
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Botulinum toxins

Background

Botulinum toxin is produced by a spore forming anaerobic bacteria, *Clostridium botulinum*. There are seven different serotypes, each with different potencies. Serotypes A and B are commercially available. Botulinum toxins inhibit the release of acetylcholine from cholinergic junctions resulting in temporary and reversible inhibition of neurotransmitter release. Paresis of the muscles occurs two-five days post injection and lasts for up to two-three months.

There are three FD- approved commercially available botulinum neurotoxin A products, and one botulinum neurotoxin B product. Each product is manufactured differently and has different formulations and characteristics. The products are not interchangeable and have different potencies and systemic effects.

Policy statement

Disclaimer: This policy is applicable to TRICARE Prime and Select beneficiaries and may not apply to Active Duty Service Members (ADSM) under Supplemental Health Care Program (SHCP) or TRICARE Prime Remote (TPR) in accordance with TRICARE Operations Manual (TOM) Chapter 17, Section 3. Please review TOM Chapter 17, Section 3, Paragraph 2.0 onwards, regarding SHCP coverage and any TRICARE-specific exclusions included in this coverage policy to accurately determine the benefit for ADSMs.

Onabotulinum toxin A may be considered medically necessary for the following conditions:

I. Achalasia as indicated by all of the following:
   a. Confirmed by esophageal manometry
   b. Failure of or patient not a candidate for pneumatic dilation or surgical myotomy
   c. Failure of pharmacologic treatment
   d. Other causes of dysphagia, such as peptic stricture, carcinoma, lower esophageal ring, or extrinsic compression have been rules out by upper gastrointestinal endoscopy
   e. Progressive dysphagia for liquids and solids

II. Anal fissure as indicated by all of the following:
   a. At least two months of symptoms
   b. Unresponsive to conservative measures such as failure of or intolerance to topical nitrates or topical calcium channel blockers

III. Blepharospasm as indicated by all of the following:
   a. Age 12 or older
   b. One of the following types of blepharospasm:
      i. Benign essential blepharospasm
      ii. Associated with dystonia
      iii. Associated with facial nerve (cranial nerve VII) disorders such as Bell's palsy
IV. Cervical dystonia (spasmodic torticollis) as indicated by all of the following:
   a. Age 16 or older
   b. Neck pain or abnormal head position causing adverse effect on daily functioning
   c. No fixed contractures causing decreased neck range of motion
V. Hemifacial spasm
VI. Hyperhidrosis (axillary or palmar) as indicated by all of the following:
   a. Age 18 or older
   b. Hyperhidrosis disease severity scale score of 2 or greater
   c. Inadequate response to one or more months of topical treatment, or patient intolerant to topical treatment due to unacceptable skin irritation
   d. Secondary causes of hyperhidrosis have been evaluated, and, if necessary, treated
VII. Laryngeal dystonia as indicated by all of the following:
   a. Adductor-type spasmodic dysphonia confirmed by fiberoptic laryngoscopy
   b. Moderate to severe difficulty in phonation
VIII. Chronic migraine headache as indicated by all of the following:
   a. Age 18 or older
   b. Migraine headache frequency occurring at least 15 days per month for three or more months
   c. Migraine headaches lasting four-72 hours, as indicated by five or more attached with all of the following:
      i. Headache symptoms, as indicated by two or more of the following:
         a) Aggravation by or causing avoidance of routine physical activity
         b) Moderate or severe pain intensity
         c) Pulsating quality
         d) Unilateral location
      ii. Migraine associated symptoms, as indicated by nausea or photophobia
      iii. Other potential causes of headaches have been ruled out
   d. Use of preventive medication (such as beta-blockers, tricyclic antidepressant, anticonvulsant) has been ineffective or not tolerated for at least 3 months
IX. Motor tics, as indicated by all of the following:
   a. Age 16 or older
   b. Patient unable to suppress tics
   c. Tics cause interference with daily functioning
X. Oromandibular dystonia
XI. Sialorrhea
XII. Spasticity in a child with cerebral palsy receiving rehabilitation

XIII. Upper or lower extremity spasticity in individual age two years or older
XIV. Strabismus, as indicated by all of the following:
   a. Age 12 or older
   b. Deviation of 50 prism diopters or less
   c. Not due primarily to Duane syndrome with lateral rectus weakness
   d. Not due primarily to restrictive strabismus
   e. Not due primarily to secondary strabismus caused by prior surgical over-recession of antagonist muscle
XV. Upper extremity focal dystonia, as indicated by all of the following:
   a. Age 16 or older
   b. Extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning
   c. No prior surgical treatment
XVI. Overactive bladder with or without urgency urinary incontinence, as indicated by all of the following:
   a. Age 18 or older
   b. Failure of or intolerance to anticholinergic medication
   c. No acute urinary retention
   d. No acute urinary tract infection
XVII. Urinary incontinence in adults due to neurogenic detrusor overactivity, as indicated by all of the following:
   a. Condition secondary to spinal cord injury, spinal dysraphism, or neurologic disease
   b. Failure of or intolerance to pharmacologic therapy including anticholinergic medication
   c. No acute urinary retention unless patient receiving regular clear intermittent catherterization
   d. No acute urinary infection
XVIII. Urinary incontinence in children due to neurogenic detrusor overactivity, as indicated by all of the following:
   a. Age five to 18 years
   b. Condition secondary to spinal cord injury, spinal dysraphism, or transverse myelitis
   c. Failure of or intolerance to pharmacologic therapy including anticholinergic medication
   d. No acute urinary tract infection

Incobotulinum toxin A may be considered medically necessary for the following conditions:
I. Blepharospasm, as indicated by all of the following:
   a. Age 18 years or older
   b. Diagnosis of benign essential blepharospasm
   c. No neuromuscular disease (e.g. myasthenia gravis)
II. Cervical dystonia (spasmodic torticollis), as indicated by all of the following:
   a. Age 18 years or older

   b. Neck pain or abnormal head position causing adverse effect on daily functioning
   c. No fixed contractures causing decreased neck range of motion
   d. No neuromuscular disease (e.g. myasthenia gravis)
III. Sialorrhea, chronic, as indicated by all of the following:
   a. Age two years or older
   b. Symptom duration at least three months
IV. Upper limb spasticity in adult
V. Upper limb spasticity in child, as indicated by all of the following:
   a. Age two-17 years
   b. Not caused by cerebral palsy

Abobotulinum toxin A may be considered medically necessary for the following conditions:

I. Blepharospasm, as indicated by all of the following:
   a. Age 18 years or older
   b. Diagnosis of benign essential blepharospasm
   c. No neuromuscular disease (e.g. myasthenia gravis)
II. Cervical dystonia (spasmodic torticollis), as indicated by all of the following:
   a. Age 16 years or older
   b. Neck pain or abnormal head position causing adverse effect on daily functioning
   c. No fixed contractures causing decreased neck range of motion
   d. No neuromuscular disease (e.g. myasthenia gravis)
III. Hemifacial spasm
IV. Hyperhidrosis (axillary), as indicated by all of the following:
   a. Age 18 or older
   b. Hyperhidrosis disease severity scale score of 2 or greater
   c. Inadequate response to one or more months of topical treatment, or patient intolerant to topical treatment due to unacceptable skin irritation
   d. Secondary causes of hyperhidrosis have been evaluated, and, if necessary, treated
V. Sialorrhea
VI. Spasticity in a child with cerebral palsy receiving rehabilitation
VII. Upper or lower extremity spasticity in individual age two years or older
VIII. Upper extremity dystonia, as indicated by all of the following:
   a. Age 16 or older
   b. Extremity pain or abnormal hand or forearm position causing adverse effect on daily functioning
   c. No prior surgical treatment

Rimabotulinum toxin B may be considered medically necessary for the following conditions:

I. Cervical dystonia (spasmodic torticollis) and all of the following:
   a. Age 16 or older
   b. Neck pain or abnormal head position causing adverse effect on daily functioning
   c. No fixed contractures causing decreased neck range of motion

d. No neuromuscular disease (e.g. myasthenia gravis)

II. Sialorrhea due to neurologic disease

Limitations of coverage

I. No active infection at site of injection
II. Unproven for treatment of lower back pain/lumbago
III. Unproven for treatment of episodic migraine, chronic daily headache, cluster headache, cervicogenic headache, and tension-type headache
IV. Unproven for treatment of muscle spasms secondary to cervical degenerative disc disease and spinal column stenosis
V. Unproven for temporomandicular joint syndrome
VI. Cosmetic indications, such as treatment of frown lines or brow furrows are excluded from coverage per TRICARE policy

TRICARE Policy Manual (TPM)

Chapter 7, Section 27.1

4.0 Policy

4.1 Botulinum toxin A (AbobotulinumtoxinA/OnabotulinumtoxinA/IncobotulinumtoxinA), Botulinum toxin B (RimabotulinumtoxinB), and any other Federal Drug Administration (FDA) approved botulinum toxin injectable drugs may be considered for cost-sharing for their FDA approved indications, unless otherwise excluded by the program.

4.2 Botox® (OnabotulinumtoxinA-chemodenervation-Current Procedural Terminology (CPT) procedure code 46505) may be considered for off-label cost-sharing for the treatment of chronic anal fissure unresponsive to conservative therapeutic measures, effective May 1, 2007.

4.3 Botulinum toxin A injections may be considered for off-label cost-sharing for the treatment of spasticity resulting from Cerebral Palsy (CP), effective November 1, 2008.

4.4 Botox® (OnabotulinumtoxinA) and Myobloc® (RimabotulinumtoxinB) injections may be considered for off-label cost-sharing for the treatment of sialorrhea associated with Parkinson's disease patients who are refractory to, or unable to tolerate, systemic anticholinergics, effective October 1, 2009.

4.5 Botox® (OnabotulinumtoxinA) injections for laryngeal dystonia (adductor spasmodic dysphonia) and oromandibular dystonia (jaw-closing dystonia) may be considered for cost-sharing.

4.6 Botox® (OnabotulinumtoxinA) injections may be considered for off-label cost-sharing for the treatment of palmar hyperhidrosis that is refractory to topical and pharmacological therapies, effective January 1, 2013.

4.7 Off-label use. Effective July 27, 2012, off-label uses of Botulinum toxin A (AbobotulinumtoxinA/OnabotulinumtoxinA/IncobotulinumtoxinA), Botulinum toxin B (Rimabotulinumtoxin B), and any other FDA approved botulinum toxin injectable drugs may be approved for cost-sharing by the contractor in accordance with Chapter 8, Section 9.1, paragraph 2.2.5 .

5.0 Exclusions

5.1 Botulinum toxin A injections are unproven for the following indications:

- Lower back pain/lumbago.
- Episodic migraine, chronic daily headache, cluster headache, cervicogenic headache, and tension-type headache.

5.2 Botox® (OnabotulinumtoxinA-chemodenervation-CPT procedure code 64612) for the treatment of muscle spasms secondary to cervical degenerative disc disease and spinal column stenosis is unproven.
5.3 Botulinum toxin A used for cosmetic indications (e.g., frown lines and brow furrows) is excluded from coverage.
5.4 Botulinum toxin A used for the treatment of myofascial pain dysfunction syndrome, also known as temporomandibular joint (TMJ) syndrome, is unproven.

Coding information

Code	Description
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB, 100 units
J0588	Injection, incobotulinumtoxinA, 1 unit

References

1. TRICARE Policy Manual Chapter 7, Section 27.1 TRICARE Manuals - Display Chap 7 Sect 27.1 (Change 119, Nov 1, 2023) (health.mil)
2. MCG Health. Ambulatory Care 29th edition. AbobotulinumtoxinA ACG: A-0620 (AC) Last update: 06/13/2025
3. MCG Health. Ambulatory Care 29th edition. IncobotulinumtoxinA ACG: A-0988 (AC) Last update: 06/13/2025
4. MCG Health. Ambulatory Care 29th edition. OnabotulinumtoxinA ACG: A-0296 (AC) Last update: 06/13/2025
5. MCG Health. Ambulatory Care 29th edition. RimabotulinumtoxinB ACG: A-0620 (AC) Last update: 06/13/2025

Review History:

December 2023: Updated references

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